



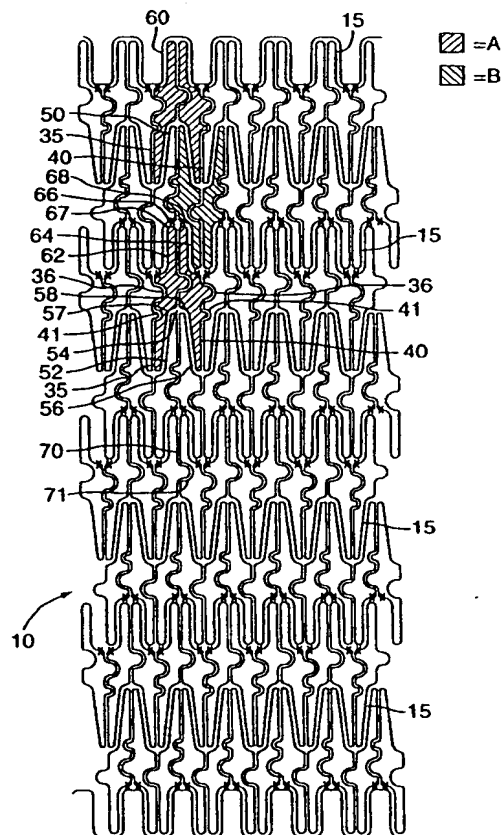
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: EXPANDABLE STENT

## (57) Abstract

An expandable stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of intersecting members arranged to define a first repeating pattern comprised of a polygon having a pair of side walls substantially parallel to the longitudinal axis, each side wall comprising first and second flexure means of the same phase with respect to the longitudinal axis, a concave-shaped first wall having a first apex and a convex-shaped second wall having a second apex, the first wall and the second wall connecting the side walls, at least one of the first apex and the second apex being substantially flat, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent.



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## EXPANDABLE STENT

### TECHNICAL FIELD

5           The present invention relates to an expandable stent.

### BACKGROUND ART

          Stents are generally known. Indeed, the term "stent" has been used interchangeably with terms such as "intraluminal vascular graft" and "expandable prosthesis". As used throughout this specification the term "stent" is intended to have a broad meaning and encompasses any expendable prosthetic device for  
10           implantation in a body passageway (e.g. a lumen or artery).

          In the past eight to ten years, the use of stents has attracted an increasing amount of attention due the potential of these devices to be used, in certain cases,  
15           as an alternative to surgery. Generally, a stent is used to obtain and maintain the patency of the body passageway while maintaining the integrity of the passageway. As used in this specification, the term "body passageway" is intended to have a broad meaning and encompasses any duct (e.g., natural or iatrogenic) within the human body and can include a member selected from the  
20           group comprising: blood vessels, respiratory ducts, gastrointestinal ducts and the like.

          Initial stents were self-expanding, spring-like devices which were inserted in the body passageway in a contracted state.

          In the case of self-expanding, spring-like devices, when released, the stent  
25           would automatically expand and increase to a final diameter dependent on the size of the stent and the elasticity of the body passageway. An example of such a stent is known in the art as the Wallstent<sup>TM</sup>.

          The self-expanding stents were found by some investigators to be deficient since, when deployed, they could place undue, permanent stress on the  
30           walls of the body passageway. Further, upon expansion, the stent would shorten in length in an unpredictable fashion thereby reducing the reliability of the stent. This led to the development of various stents which were controllably expandable at the target body passageway so that only sufficient force to maintain the patency of the body passageway was applied in expanding the stent.

Generally, in the balloon-deployable systems, a stent, in association with a balloon, is delivered to the target area of the body passageway by a catheter system. Once the stent has been properly located (for example, for intravascular implantation the target area of the vessel can be filled with a contrast medium to facilitate visualization during fluoroscopy), the balloon is expanded thereby expanding the stent by plastic deformation so that the latter is urged in place against the body passageway. As indicated above, the amount of force applied is at least that necessary to maintain the patency of the body passageway. At this point, the balloon is deflated and withdrawn within the catheter, and subsequently removed. Ideally, the stent will remain in place and maintain the target area of the body passageway substantially free of blockage (or narrowing).

A stent which has gained some notoriety in the art is known as the Palmaz-Schatz™ Balloon Expandable Stent (hereinafter referred to as "the Palmaz-Schatz stent"). This stent is discussed in a number of patents including United States patents 4,733,665, 4,739,762, 5,102,417 and 5,316,023, the contents of each of which are hereby incorporated by reference.

Another stent which has gained some notoriety in the art is known as the Gianturco-Roubin Flex-Stent™ (hereinafter referred to as "the Gianturco-Roubin stent"). This stent is discussed in a number of patents, including United States patents 4,800,882, 4,907,336 and 5,041,126, the contents of each of which are hereby incorporated by reference.

Other types of stents are disclosed in the following patents:

United States patent 5,035,706 (Gianturco et al.),  
United States patent 5,037,392 (Hillstead),  
United States patent 5,147,385 (Beck et al.),  
United States patent 5,282,824 (Gianturco),  
Canadian patent 1,239,755 (Wallsten), and  
Canadian patent 1,245,527 (Gianturco et al.).

the contents of each of which are hereby incorporated by reference.

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While these prior art stents have achieved a varying degree of success, the art is constantly in need of new stents having improved flexibility and stability while being able to be readily implanted with little or no trauma to the target lumen.

5 An improved expendable stent is described in the following copending patent applications:

Canadian patent application number 2.134.997 (filed November 3, 1994);

Canadian patent application number 2.171.047 (filed March 5, 1996);

10 Canadian patent application number 2.175.722 (filed May 3, 1996);

Canadian patent application number 2.185.740 (filed September 17, 1996);

Canadian patent application number 2.192.520 (filed December 10, 1996);

15 International patent application PCT/CA97/00151 (filed March 5, 1997);  
and

International patent application PCT/CA97/00152 (filed March 5, 1997);

the contents of each of which are hereby incorporated by reference (hereinafter  
20 collectively referred to as "the Divysio applications"). Generally, the stent  
illustrated in the Divysio patent applications comprises a tubular wall disposed  
between the proximal end and the distal end. The tubular wall has a longitudinal  
axis and a porous surface defined by a plurality intersecting members arranged  
to define a first repeating pattern. The first repeating pattern comprises a  
25 polygon having a pair of side walls substantially parallel to the longitudinal axis.  
A first concave-shaped wall and a second convex-shaped wall connect the side  
walls. The stent is expendable from a first, contracted position to a second,  
expanded position upon the application of a radially outward force exerted on the  
stent.

30 In the field of stent design, there is an ongoing need to develop a stent  
which has a combination of the the following properties:

- (i) flexibility in the unexpanded state of the stent to facilitate delivery of the stent via tortuous pathway (if necessary) to the the target lumen;
- (ii) radial rigidity of the stent in the expanded (i.e., deployed) state to mitigate against the occurrence of collapse or recoil of the stent; and
- (iii) relative ease of expansion of the stent from the unexpanded state to the expanded state to reduce the likelihood of injuring the target lumen during expansion.

The stent illustrated in the Divysio applications provides an desirable combination of these features. Notwithstanding this, it would be desirable to further improve feature (iii), i.e., the ease of expansion of the stent.

#### 15 DISCLOSURE OF THE INVENTION

It is an object of the present invention to provide a novel expandable stent. Accordingly, the present invention provides an expandable stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality intersecting members arranged to define a first repeating pattern comprised of a polygon having a pair of side walls substantially parallel to the longitudinal axis, each side wall comprising first and second flexure means of the same phase with respect to the longitudinal axis, a concave-shaped first wall having a first apex and a convex-shaped second wall having a second apex, the first wall and the second wall connecting the side walls, at least one of the first apex and the second apex being substantially flat, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent.

Thus, we have now discovered that, of the various flexure means disclosed in International patent applications PCT/CA97/00151 and PCT/CA97/00152 (both filed March 5, 1997), the use of a specific subset thereof

in the side walls of the polygon of the first repeating pattern leads to a surprising and unexpected reduction in the expansive forces needed to transform the stent from the unexpanded state to the expanded state. The enhancement of this property can be achieved without compromising the desirable flexibility and radial rigidity properties of stent discussed above (i.e., features (i) and (ii), respectively). Generally, the specific subset is the combination of first and second flexure means of the same phase with respect to the longitudinal axis of the tubular wall of the stent. As used throughout this specification, the term "first and second flexure means of the same phase" is intended to mean that each flexure means comprises a lateral section in the side wall (this term is used throughout this specification with the term longitudinal strut") with the proviso that, for a given longitudinal strut, the lateral section of each flexure means departs from the longitudinal axis of the strut in the same direction. By "lateral section" is meant a section of the longitudinal strut which is bowed in or out of (i.e., radially from) the strut. Other than this, the specific shape of the first and second flexure means disposed in the longitudinal strut is not particularly restricted. The apex of the lateral section may be pointed, rounded or substantially flat.

Of course, the first and second flexure means should act to confer lateral flexibility to the unexpanded stent by allowing diametrically opposed pairs of the longitudinal struts to undergo substantially complementary extension and compression. The term "diametrically opposed pairs of the longitudinal struts", as used in this specification, is intended to have a broad meaning. Thus, the "pair" can include opposed struts in the same horizontal plane (e.g., the same ring of polygons) or in different horizontal planes (e.g., one strut in a first ring of polygons and the other diametrically opposed strut in a second ring of polygons above or below the first ring).

In a given longitudinal strut, the first and second flexure means may be symmetric or asymmetric (in the case of asymmetric this includes two sections of the same shape but different size and two sections of different and size).

As described in various of the Divysio patent applications, practically, the flexure means confers lateral flexibility to the unexpanded stent by allowing

diametrically opposed pairs of the longitudinal struts to undergo substantially complementary extension and compression. If one considers a stent in a flexed state, a first longitudinal strut disposed at the tangent of the bend (i.e., in two dimensions) will expand in response to the bending moment. In contrast, a  
5 second longitudinal strut disposed diametrically opposite (this can mean above, below or in the same radial plane as) the first longitudinal strut will compress in response to the bending moment. Generally, the degree of extension and compression will be substantially complementary. In other words, in most cases, the first longitudinal strut will expand and lengthen a first distance and the second  
10 longitudinal strut will compress and shorten a second distance. Preferably, the first distance is greater than the second distance and most preferably, the sum of the first distance and the second distance is substantially equal to the sum of the original lengths of the first longitudinal strut and the second longitudinal strut.

Preferably, for a given circumferential ring of polygons in the first  
15 repeating pattern, the first and second flexure means are in the same phase with respect to the longitudinal axis of the tubular wall. More preferably, phase of the first and second flexure means is reversed with respect to adjacent circumferential rings of polygons in the tubular wall - this is illustrated in Figure 1 of the present application.

20 In one preferred embodiment, one or both of the first and second flexure means used in a given longitudinal strut is designed to have a curved section with an arc of about  $180^\circ$  - i.e., this is illustrated in Figure 1 of the present application. The term "arc" denotes the angle from one end of the curved section to the other about the radial point of the curved section. In another preferred embodiment,  
25 one or both of the first and second flexure means used in a given longitudinal strut is designed to have a curved section wherein each curved section has an arc of greater than  $180^\circ$  - i.e., the shape of the curved section is in the form of an omega design. Further, the pair of the first and second flexure means used in a given longitudinal strut can be of the same size or of differing size (this is  
30 illustrated in Figure 1 of the present application). the latter being the most preferred embodiment.



In one preferred embodiment, the series of longitudinal struts, each containing the first and second flexure means, comprise all substantially longitudinal struts which define to polygon of the repeating pattern defined hereinabove.

5 As used throughout this specification, the terms "concave-shaped" and "convex-shaped" are intended to have a broad meaning and a shape having apex. Thus, the first wall has a first apex and the second wall has a second apex. As will be readily apparent, the first apex (i.e., of the concave-shaped first wall) is directed into the polygon whereas the second apex (i.e., of the convex-shaped  
10 second wall) is directed away from the polygon.

As described in various of the Divysio applications, the use of the first repeating pattern including at least one of the first apex and second apex being substantially flat results in an improved stent. The advantages associated with the use of such a such a first repeating pattern include the following:

- 15
1. the force required to expand the stent is substantially reduced;
  2. the stent is subjected to less traumatic stress during expansion;
  - 20 3. plastic deformation of the stent during expansion is facilitated;
  4. construction of the stent is facilitated; and
  5. upon expansion of the stent, warpage of the first apex and the second apex is obviated or mitigated.

25 The provision of at least one of the first apex and the second apex being substantially flat usually results in the apex of the concave-shaped first wall and/or the convex-shaped second wall having a pair of shoulders. Preferably, these shoulders are rounded. The provision of such round shoulders results in the  
30 following additional advantages:

6. mitigation of potential trauma to the target body passageway from: (i) endoluminal contents within the passageway, and (ii) the contours of the passageway;
7. the resulting expanded stent is more stream-lined and flow-directed which mitigates potential trauma to the target body passageway;
8. further reduction in the force required to expand the stent;
9. an improved stent expansion ratio is achieved (i.e. ratio of expanded stent diameter at maximum expansion to unexpanded stent diameter);
10. upon expansion of the stent, the concave-shaped first wall and the convex-shaped second wall are in a substantially orthogonal relationship to the longitudinal axis thereby improving the rigidity of the stent (this is very important to mitigate the occurrence of stent recoil); and
11. the pattern of the expanded stent improves the rheology of fluid flow in the body passageway.

When the stent of the present invention includes the above-mentioned first repeating pattern, it is preferred to provide a connecting strut between the first apex and the second apex. Generally, the connecting strut will be substantially longitudinal (i.e., it will be parallel to the longitudinal axis of the stent). This feature mitigates lifting of the shoulders referred to above as the stent is flexed, for example, when passing the stent through a curved body passageway. The result of this is that potential trauma to the body passageway is mitigated since scraping of the body passageway by the shoulders is mitigated.

In a preferred embodiment, the connecting strut is curved with respect to the longitudinal axis (this is described and illustrated in more detail in various of the Divysio applications). In one preferred embodiment, the strut is sufficiently curved to have a length of up to about 35%, more preferably up to about 15%, even more preferably in the range of from about 2% to about 8%, most preferably in the range of from about 3% to about 7%, greater than the distance

between the first apex and the second apex. In another preferred embodiment, the connecting strut comprises a third flexure means. The discussion above with respect to the design of the first and second flexure means applies equally here with respect to the design of the third flexure means. Preferably, for a given polygon in the repeating pattern, the third flexure means is in the same phase as the first and second flexure means disposed in the pair of side walls (or longitudinal struts) comprised in the polygon. This feature improves the lateral flexibility of the stent thereby facilitating implantation thereof. In some cases, the curvature may be designed to comprise the flexure means discussed above.

In other words, the shape of the curvature may be designed substantially complementary extension and compression of the connecting strut upon flexure of the stent.

The stent of the present invention may be mono-tubular or bifurcated. Preferably, the present stent is monotubular.

The stent of the present invention (bifurcated or mono-tubular) can further comprise coating material thereon. The coating material can be disposed continuously or discontinuously on the surface of the stent. Further, the coating may be disposed on the interior and/or the exterior surface(s) of the stent. The coating material can be one or more of a biologically inert material (e.g., to reduce the thrombogenicity of the stent), a medicinal composition which leaches into the wall of the body passageway after implantation (e.g., to provide anticoagulant action, to deliver a pharmaceutical to the body passageway and the like) and the like.

The stent is preferably provided with a biocompatible coating, in order of minimize adverse interaction with the walls of the body vessel and/or with the liquid, usually blood, flowing through the vessel. The coating is preferably a polymeric material, which is generally provided by applying to the stent a solution or dispersion of preformed polymer in a solvent and removing the solvent. Non-polymeric coating material may alternatively be used. Suitable coating materials, for instance polymers, may be polytetrafluoroethylene or silicone rubbers, or polyurethanes which are known to be biocompatible. Preferably however the polymer has zwitterionic pendant groups, generally

ammonium phosphate ester groups, for instance phosphoryl choline groups or analogues thereof. Examples of suitable polymers are described in International application number WO-A-93/16479 and WO-A-93/15775. Polymers described in those specifications are hemo-compatible as well as generally biocompatible and, in addition, are lubricious. It is important to ensure that the surfaces of the stent are completely coated in order to minimize unfavourable interactions, for instance with blood, which might lead to thrombosis.

This good coating can be achieved by suitable selection of coating conditions, such as coating solution viscosity, coating technique and/or solvent removal step.

In another embodiment of the invention, the stent may be joined to a polymer material. Specifically, a polymer material may be extruded onto the stent in such a manner that it envelops at least a portion of the stent. This technique may be used to join two or more stents with a flexible polymeric tube. This technique may also be used to join a stent to another prosthetic device such as a tube, a graft and the like. Thus, in this embodiment of the invention, the stent is incorporated into an endoluminal prosthesis.

In yet another embodiment of the invention, the stent may be secured (e.g. by suturing) to an existing endoluminal prosthesis such as Gortex<sup>TM</sup> material or to biological material such as basilic vein. In this regard, securing of the stent to the existing endoluminal prosthesis or biological material may be facilitated by designing the stent such that an end of the stent comprises an annular row of the above-mentioned polygons is having a convex-shaped wall with a flat apex.

Embodiments of the present invention will be described with reference to the accompanying drawing, in which:

Figure 1 illustrates a two dimensional representation of a preferred embodiment of a repeating pattern useful in the stent of the present invention.

With reference to Figure 1, there is illustrated a preferred embodiment of a two dimensional representation of a repeating pattern useful in the present stent. The repeating pattern is manifested in a wall 10 disposed between the proximal end and the distal end of the stent (not shown). As illustrated, tubular wall 10 is porous. The porosity of tubular wall 10 is defined by a plurality of intersecting

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members 15. Intersecting members 15 define a first repeating pattern designated A in Figure 1.

As illustrated and with further reference to Figure 1, repeating pattern A is a polygon comprising a pair of side walls 35,40. Side walls 35,40 are substantially parallel to a longitudinal access of the stent and thus, side walls 35,40 may be considered to be longitudinal struts. Side walls 35,40 are connected by a concave-shaped wall 50 and a convex-shaped wall 60. Further, side walls 35,40 include a pair of curved sections 36,41. It should be noted that each curved section 36,41 in Figure 1 has an arc of about 180°. Further, as illustrated, concave-shaped wall 50 and concave-shaped wall 60 are not equidistance along an access normal to the longitudinal access of the stent (not shown).

As illustrated, concave-shaped wall 50 is made up of a trio of segments 52,54,56. In the illustrated embodiment, segment 54 is the apex of concave-shaped wall 50. As is evident, segment 54 is a flat apex and result in the provision of a pair of substantially rounded shoulders 57,58. Convex-shaped wall 60 is made up of a trio of segments 62,64,66. In the illustrated embodiment, segment 64 is apex of convex-shaped wall 60 and comprises a pair of rounded shoulders 67,68.

It will be appreciated by those of skill in the art that the provision of first repeating pattern A, as illustrated, necessarily defines and provides for a second repeating pattern B. It will also be appreciated by those of skill in the art that second repeating pattern B is a mirror image of first repeating pattern A taken along an access (not shown) substantially normal to the longitudinal access of the stent. Thus, in the illustrated embodiment, adjacent rows of repeating pattern A and repeating pattern B may be considered to be interlocking polygons (or "arrowheads").

As will be apparent with reference to Figure 1, the phase of curved sections 36,41 in a circumferential ring of repeating pattern A is the same within the ring, and is reversed with respect to the phase of curved sections 36,41 in an adjacent circumferential ring of repeating pattern B.

With further reference to repeating pattern A in Figure 1, a strut 70 has been added to connect segment 54 of concave-shaped wall 50 and segment 64 of 15 convex-shaped wall 60 - this may be regarded as a "closed design". Further, strut 70 includes a curved section 71 along the length thereof. Thus, strut 70 may  
5 be considered as a relatively thin retention segment which reconciles the need for retaining flexibility in the strut with mitigating lifting of rounded shoulders 57,58 when the strut is delivered to the target for a passageway through a relatively tortuous route. As will be apparent to those of skill in the art, the provision of strut 70 is optional and may be omitted. When strut 70 is omitted from repeating  
10 pattern A and/or repeating pattern B, the design may be regarded as an "open design". Thus, the terms "closed design" and "open design" are used in a relative sense.

It should be noted that curved sections 36 and 71 are of the same size and differ in size from curved section 41. A distinct advantage of the interspersion  
15 of curved sections 36,41,71 in repeating pattern A and/or repeating pattern B is that substantially uniform radial expansion of all segments in the stent will occur without specific regard to the expansion forces generated by the balloon or other means used to deploy the stent. Further, a specific design illustrated herein minimizes the force (e.g., pressure from a balloon) required to expand the stent.

As will be further apparent to those of skill in the art, curved sections 36  
20 and 41 are offset with respect to one another in a plane horizontal to the longitudinal axis of tubular wall 10. The offset nature of these curved sections serves to increase the bending points in the stent allowing the stent to bend while avoiding bucking thereof. Thus, the staged distribution of curved portions over  
25 a large portion of the surface area of the stent serves to improve the flexibility of the stent.

It will be further appreciated by those of skill in the art that the shape of concave-shaped wall 50 and/or convex-shaped wall 60 can be modified without departing from the function and performance of the stent provided that at least  
30 one of concave-shaped wall 50 and convex-shaped wall 60 retain a substantially flat apex. For example, the trio of segments can be replaced by a suitable curved or arcuate wall. Alternatively, more than two segments can be used to define

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concave-shaped wall 50 and/or convex-shaped wall 60. Other modifications will be apparent to those of skill in the art.

It will be further appreciated by those of skill in the art that various walls of first repeating pattern A and second repeating pattern B may be omitted (and even desired) at selected points along the body of the stent without departing from the spirit and scope of the invention. For example, it is possible to omit one or both of side walls 35,40 at selected points along the body of the stent with a view to improving the longitudinal flexibility of the stent. Further, it is possible to omit one or more of segment 62,64,66 at selected points along the body of the stent with a view to improving the lateral flexibility of stent.

Still further, the design depicted in Figure 1 can be modified to omit, on a selected basis, first repeating pattern A and/or second repeating pattern B with a view to improving flexibility of the stent and to allow access to other structures (e.g., side branches/arteries) outside the bounds of the stent.

As discussed above, the use of flexure means, such as the curved sections referred to in Figure 1, provides the added benefit of improved flexibility of the stent in the unexpanded state. Specifically, during flexure of the stent, provision of such a feature allows the inner stent surface adjacent to bend to compress while concurrently allowing the outer stent surface adjacent to bend to extend all while maintaining substantially intact the intricate strength of the stent and avoiding buckling of the stent.

The manner by which the present stent is manufactured is not particularly restricted. Preferably, the stent is produced by laser cutting techniques applied to a tubular starting material. Thus, the starting material could be a thin tube of a metal or alloy (non-limiting examples include stainless steel, titanium, tantalum, nitinol, Elgiloy, NP35N and mixtures thereof) which would then have sections thereof cut out to leave repeating pattern A discussed above. Thus, the preferred design of the present stent is one of a tubular wall which is distinct from prior art wire mesh designs wherein wire is conformed to the desired shape and welded in place. The preferred tubular wall design of the present stent facilitates production and improves quality control by avoiding the use of welds and, instead, utilizing specific cutting techniques.

Preferably, the stent is coated with a solution of 1:2 (mole) copolymer of (methacryloyloxy ethyl)-2-(trimethylammonium ethyl) phosphate inner salt with lauryl methacrylate in ethanol (as described in Example 2 of International patent application WO-A-93/01221) as follows. The non-expanded stent may be placed  
5 in a tube having a slightly larger diameter than the stent. The tube may then be filled with coating solution and the solution allowed to drain steadily from the tube to form a completely coated stent. Immediately thereafter a stream of warm air or nitrogen may be directed through the tube at a linear velocity of 0.1.5 m/s at room temperature to 50°C for a period of 30 seconds to 5 minutes to dry the  
10 coating by evaporation of the ethanol solvent.

As an alternative or in addition (on top or underneath) to this coating, a cross-linkable coating may be used consisting of a polymer of 23 mole% (methacryloyloxy ethyl)-2-(trimethylammonium ethyl) phosphate inner salt, 47 mole % lauryl methacrylate, 5 mole %  $\gamma$ trimethoxysilylpropyl methacrylate and  
15 25 mole % of  $\gamma$ hydroxypropyl methacrylate. This may be applied to the stent by the above described technique from a 5mg/ml ethanolic solution. The solution may be dried as described above and then cured by heating at 70 to 75°C for a period of at least about 1 hour, for instance overnight. This curing generally results in substantially complete reaction of the methoxy silyl groups, either with  
20 other methoxysilyl groups or with hydroxy groups derived from the hydroxypropyl methacrylate monomer, driving off methanol. In one preferred embodiment the crosslinkable coating is applied to the cleared stent, cured and then a further coating of the lauryl methacrylate copolymer described above is applied.

25 The coated stent may be sterilised by ethylene oxide, gamma radiation or electron beam and subsequently mounted onto a balloon catheter for delivery.

The present stent can be implanted using a conventional system wherein a guidewire, catheter and balloon can be used to position and expand the stent. Implantation of mono-tubular stents is conventional and with the purview of a  
30 person skilled in the art. See, for example, any one of United States patents 4,733,665, 4,739,762, 5,035,706, 5,037,392, 5,102,417, 5,147,385, 5,282,824, 5,316,023 and any of the references cited therein or any of the references cited



hereinabove. When the present stent is constructed as a bifurcated stent, it may be implanted using the procedure outlined in the '997 patent application incorporated herein by reference. Such a bifurcated stent may be manufactured, inter alia, by any of the methods disclosed in the Canadian patent application number 2,175,720 filed in Applicant's name on May 3, 1996, the contents of which are hereby incorporated by reference.

It will be apparent to those of skill in the art that implantation of stent 10 can be accomplished by various other means. For example, it is contemplated that the stent can be made of a suitable material which will expand when a certain temperature is reached. In this embodiment, the material may be a metal alloy (e.g. nitinol) capable of self-expansion at a temperature of at least about 30°C, preferably in the range of from about 30° to about 40°C. In this embodiment, the stent could be implanted using a conventional catheter and the radially outward force exerted on the stent would be generated within the stent itself. Further, stent 10 can be designed to expand upon the application of mechanical forces other than those applied by a balloon/catheter. For example, it is possible to implant stent 10 using a catheter equipped with a resisting sleeve or retaining membrane which may then be removed with the catheter once the stent is in position thereby allowing the stent to expand. Thus, in this example, the stent would be resiliently compressed and would self-expanded once the compressive force (i.e. provided by the sleeve or membrane) is removed.

While this invention has been described with reference to illustrative embodiments, this description is not intended to be construed in a limiting sense. Various modifications of the illustrative embodiments, as well as other embodiments of the invention, will be apparent to persons skilled in the art upon reference to this description. It is therefore contemplated that the appended claims will cover any such modifications or embodiments.

What is claimed is:

1. An expandable stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality intersecting members arranged to define a first repeating pattern comprised of a polygon having a pair of side walls substantially parallel to the longitudinal axis, each side wall comprising first and second flexure means of the same phase with respect to the longitudinal axis, a concave-shaped first wall having a first apex and a convex-shaped second wall having a second apex, the first wall and the second wall connecting the side walls, at least one of the first apex and the second apex being substantially flat, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent.
2. The stent defined in claim 1, wherein the each of the first and second flexure means comprise lateral section disposed in each longitudinal strut.
3. The stent defined in claim 2, wherein the lateral section comprises a pointed apex.
4. The stent defined in claim 2, wherein the lateral section comprises a rounded apex.
5. The stent defined in claim 2, wherein the lateral section comprises a flat apex.
6. The stent defined in claim 5, wherein the first flexure means and the second flexure means are symmetric.
7. The stent defined in claim 5, wherein the first flexure means and the second flexure means are asymmetric.

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8. The stent defined in claim 7, wherein the first flexure means and the second flexure means have substantially the same shape and differing size.
9. The stent defined in claim 7, wherein the first flexure means and the second flexure means have differing shape and size.
10. The stent defined in any one of claims 6-9, wherein the first lateral section and the second lateral section have substantially the same shape and differing size.
11. The stent defined in any one of claims 1-10, wherein one or both of the first flexure means and the second flexure means comprises a curved section having an arc of greater than 180°.
12. The stent defined in any one of claims 1-10, wherein one or both of the first flexure means and the second flexure means comprises a curved section having an arc of about 180°.
13. The stent defined in any one of claims 11-12, wherein the curved sections are of substantially the same size.
14. The stent defined in any one of claims 11-12, wherein the curved sections are of different size.
15. The stent defined in any one of claims 1-14, wherein the stent is constructed of stainless steel.
16. The stent defined in any one of claims 1-14, wherein the stent is constructed of a self-expanding material.
17. The stent defined in claim 16, wherein the self-expanding material is natural.

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18. The stent defined in claim 16, wherein the self-expanding material expands at a temperature of greater than about 30°C.

19. The stent defined in claim 16, wherein the self-expanding material expands at a temperature of in the range of from about 30° to about 40°C.

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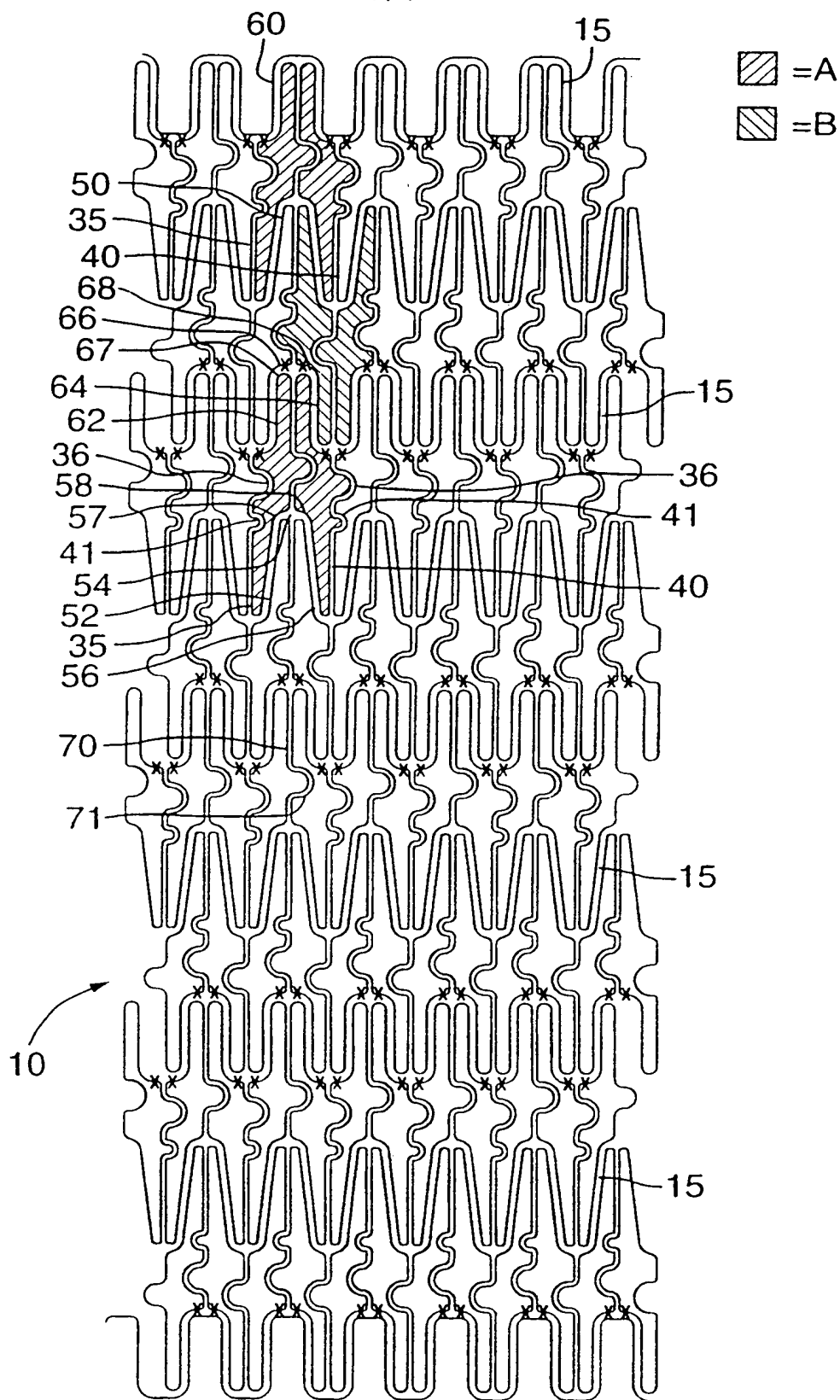


FIG.1

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 98/00835

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 297 08 879 U (JOMED IMPLANTATE) 31 July 1997  see figures 2,3 see page 6, line 1 - line 13 ---	1,2,4,6, 7,9, 11-14
X	WO 96 03092 A (MEDINOL LTD ;BRUN HEIDI M (IL)) 8 February 1996 cited in the application see page 4, line 20 - page 5, line 16 see page 7, line 21 - line 30 see figures 1,7,8 ---	1,2,4-6, 12,13
X	DE 297 02 671 U (JOMED IMPLANTATE) 10 April 1997 see figures 2-5,7-10 see claims 1,15 ---	1-4,6, 12,13
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

**\* Special categories of cited documents :**

- "A" document defining the general state of the art which is not considered to be of particular relevance
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- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "3" document member of the same patent family

Date of the actual completion of the international search

19 November 1998

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## INTERNATIONAL SEARCH REPORT

Inter national Application No

PCT/CA 98/00835

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 97 32544 A (DIVYSIO SOLUTIONS LTD ;PENN IAN M (CA); RICCI DONALD R (CA)) 12 September 1997 see figure 10 see figures 12A-I see claims 1,2 see claims 14-17 see claims 31-34 see claims 35-39 see page 16, line 19 - page 18, line 31 ---	1-19
P,X	WO 97 32543 A (DIVYSIO SOLUTIONS LTD ;PENN IAN M (CA); RICCI DONALD R (CA)) 12 September 1997 see figure 10 see figures 12A-I see claims 1-23 -----	1-19

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte: Jnal Application No

PCT/CA 98/00835

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
DE 29708879	U	31-07-1997	NONE	
WO 9603092	A	08-02-1996	US 5733303 A AT 170733 T AU 3270695 A BR 9508353 A CA 2195783 A CN 1158078 A CZ 9700191 A DE 19581503 C DE 19581503 T DE 29521193 U DE 29521205 U DE 29521206 U DE 69504659 D DK 8097 A EP 0762856 A EP 0846448 A EP 0846449 A EP 0846450 A EP 0846451 A EP 0846452 A FI 970316 A GB 2304587 A,B GB 2315415 A,B JP 10503676 T LT 97022 A,B LU 90031 A NO 970289 A PL 318270 A SE 9700206 A SI 9520079 A SK 11597 A	31-03-1998 15-09-1998 22-02-1996 04-11-1997 08-02-1996 27-08-1997 11-06-1997 02-04-1998 16-01-1997 24-10-1996 19-09-1996 19-09-1996 15-10-1998 19-02-1997 19-03-1997 10-06-1998 10-06-1998 10-06-1998 10-06-1998 10-06-1998 07-03-1997 26-03-1997 04-02-1998 07-04-1998 25-11-1997 16-04-1997 26-03-1997 26-05-1997 28-02-1997 31-12-1997 08-10-1997
DE 29702671	U	10-04-1997	WO 9835634 A	20-08-1998
WO 9732544	A	12-09-1997	CA 2171047 A CA 2175722 A CA 2185740 A AU 1864397 A	06-09-1997 04-11-1997 18-03-1998 22-09-1997



# INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte: onal Application No

PCT/CA 98/00835

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9732544 A		AU 1864497 A	22-09-1997
		WO 9732543 A	12-09-1997
WO 9732543 A	12-09-1997	CA 2171047 A	06-09-1997
		CA 2175722 A	04-11-1997
		CA 2185740 A	18-03-1998
		AU 1864397 A	22-09-1997
		AU 1864497 A	22-09-1997
		WO 9732544 A	12-09-1997

